

# **EXHIBIT A**



[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

## Premarket Approval (PMA)



[510\(k\)](#)<sup>7</sup> [DeNovo](#)<sup>8</sup> [Registration & Listing](#)<sup>9</sup> [Adverse Events](#)<sup>10</sup> [Recalls](#)<sup>11</sup> [PMA](#)<sup>12</sup> [HDE](#)<sup>13</sup> [Classification](#)<sup>14</sup> [Standards](#)<sup>15</sup>  
[CFR Title 21](#)<sup>16</sup> [Radiation-Emitting Products](#)<sup>17</sup> [X-Ray Assembler](#)<sup>18</sup> [Medsun Reports](#)<sup>19</sup> [CLIA](#)<sup>20</sup> [TPLC](#)<sup>21</sup>

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[Back to Search Results](#)

Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the [original PMA](#)<sup>23</sup> record for more information.

<b>Device</b>	NUCLEUS COCHLEAR IMPLANT SYSTEM
<b>Generic Name</b>	Implant, Cochlear
<b>Applicant</b>	Cochlear Americas 13059 East Peakview Avenue Centennial, CO 80111
<b>PMA Number</b>	P970051
<b>Supplement Number</b>	S137
<b>Date Received</b>	11/23/2015
<b>Decision Date</b>	07/08/2016
<b>Product Code</b>	<a href="#">MCM</a> <sup>24</sup>
<b>Advisory Committee</b>	Ear Nose & Throat
<b>Supplement Type</b>	Normal 180 Day Track
<b>Supplement Reason</b>	Change Design/Components/Specifications/Material
<b>Expedited Review Granted?</b>	No
<b>Combination Product</b>	No

### Approval Order Statement

Approval requested for 1) a change in indications to allow MRI of implant recipients at 1.5T with the implant magnet in place for CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), and CI24RE(ST) provided that a Cochlear-supplied MRI kit is used; 2) a change in indications to allow MRI of implant recipients at 3.0T with the implant magnet removed for CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), and CI24RE(ST); and 3) consolidation of MRI-related labeling into a single document that provides appropriate instructions for the following Cochlear-manufactured implants: CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), CI24RE(ST), CI24R(CA), CI24R(CS), CI24R(ST), CI24M, and CI 11+11+2M.

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9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
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11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
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16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
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21. </scripts/cdrh/cfdocs/cfTPLC/tplc.cfm>
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